

REMARKS

Claims 1-12 are pending. Applicant elects with traverse Group II (claims 1-4 and SEQ ID NO: 36) for examination on the merits. Applicant reserves the right to prosecute nonelected subject matter in a further patent application.

The amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry. For example, “low allergenicity” is supported by the title of the application and specifies that the claimed flour is less allergenic than wheat flour.

Notwithstanding the above election, reconsideration of the restriction requirement is requested because examination of all pending claims would not constitute a serious burden. Although the inventions identified by the Examiner are separately patentable, both the need for compact prosecution and the public interest would be served by examination of all claims in a single application.

Applicant also disagrees with the allegation in the Action that the pending claims lack unity of invention, and therefore belong to different groups of inventions. Although they agree with the Examiner’s conclusion that the inventions are separately patentable, Applicant’s traversal is based on the pending claims being so linked as to form a single general inventive concept under PCT Rule 13.1. Accordingly, there is no lack of unity with regard to claims 1-9 and at least claims 5-9 should be examined in this application. Applicant submits that all of the pending claims (claims 10-12 are related to using the flour of the elected product claims) should be examined together in this application.

It is urged that two essential features of the claimed invention (especially the elected flours) appear not to have been considered by the Examiner in her finding of lack of unity: the properties (i.e., low allergenicity and ability to rise) of the flours made from the seeds of the transgenic plants. An objective of the invention is to obtain flours that have low allergenicity (hence, not flours made from wheat) but are nevertheless capable of rising like wheat flours (see Figs. 23 and 24). Obtaining this objective was the result of the inventor’s discovery that wheat storage protein having the C-terminal motif LKVAKAQQLAAQLPAMCR (SEQ ID NO:11) is essential for non-wheat flours to rise when treated with transglutaminase. Thus, the invention uses a limited number of

wheat storage proteins with the aforementioned motif that are capable of conferring the ability to rise on flours made from seeds of non-wheat plants such as rice and legumes.

Further, the Applicant has taken into account a further step to even improve the flours as aforementioned, namely targeted mutations of certain domains where amino acid residues are optionally mutated to minimize the allergenicity of the claimed flours. In order to make the flour immediately ready to use, the inventor has also expressed in the same seeds a transglutaminase. This direct expression of the transglutaminase in the seeds for making the flour led to the expression of an active enzyme in the seed.

The claimed invention thus permits the production of a non-wheat non-allergenic, rising flour that requires only the addition of yeast for rising (similar to wheat flour), but with the advantage that flours of the present invention **do not contain wheat allergens expressed in wheat seeds**.

The Examiner cites in her Office Action (page 5-6) the disclosures WO 98/08607 and US 6,517,874 as showing that the claims lack the same or corresponding special technical feature and thus do not relate to a single general inventive concept. It was stated, “Anderson O.D. (WO 98/08607) teaches a high molecular weight (HMW) glutelin from wheat that comprises SEQ ID NO: 11 . . . He teaches that HMW glutelin is important for flour quality, especially the viscoelasticity of the flour . . . He teaches transgenic plants expressing engineered HMW glutelin.” But WO 98/08607 fails to teach or suggest the claimed invention for the following reasons:

1. WO 98/08607 allegedly teaches dough, preferably wheat dough with particular viscoelasticity properties and its use in products such as breads and noodles. See page 3, first paragraph, of the Summary of the Invention. Noodles are not relevant to the rising property of dough because the dough used for noodles is not reacted with yeast for rising. The examples are limited solely to wheat flour. No examples are provided of a non-wheat flour. In fact, the sole plant mentioned is wheat.
2. Moreover, WO 98/08607 teaches artificial HMW glutenin subunits. In particular, WO 98/08607 teaches that the modification of the number of certain repeats is related to viscoelasticity. See page 3, lines 8-20. Adding certain repeats in a number higher than the native protein improves the viscoelasticity properties of the wheat dough in

which the modified protein is expressed. The repeats that appear to be preferred (SEQ ID NOS: 1-5) are extremely rich in Glutamine.

WO 98/08607 does not even consider the problem of allergens in wheat flour. It discloses transforming wheat (which is allergenic per se) with an artificial HMW glutelin in which Glutamine rich repeats (linked to allergenicity) are added. This addition of Glu rich repeats is important for the invention disclosed in WO 98/08607 which makes flour with improved characteristics (i.e., viscoelastic properties) for the manufacturing of baked products and noodles (of course, rising is irrelevant to the latter). Therefore, WO 98/08607 teaches away from making modification in HMW glutelins that are not related to improving viscoelastic properties.

US 6,517,874 is also cited. The Examiner alleged that the patent “teaches that trans-glutaminase can be added to flour blends comprising as little as 1% wheat flour to produce a baking flour mixture with favourable properties.” But US 6,517,874 fails to teach or suggest the claimed invention for the following reasons:

1. Although allegedly describing flour blends comprising **at least** 1% of wheat flour (wheat NEVER being completely absent) in column 2, US 6,517,874 does not exemplify a flour with less than 20% wheat flour (Example 2, Table 4) in the flour blends tested except in Example 1 where it is clearly shown that the absence of wheat flour in the blend makes the dough flat and hence not rising (see Table 1). In fact, the examples show that the rising properties of the flour blend treated with transglutaminase are already decreasing and not optimal with as much as 20% wheat flour in the blend.
2. Moreover, US 6,517,874 teaches that transglutaminase can be added at various stages of the blend or dough preparation. See column 3, lines 59-61. But it also clearly teaches by way of reiteration that the transglutaminase **SHOULD NOT BE GROUND** for best results.

Therefore, US 6,517,874 strongly teaches away from having transglutaminase present in the seeds before they are ground into flour or using a flour blend having less than 20% wheat flour even if the latter does not rise.

It is hence not clear how the two cited documents would obviously lead to the present invention when combining the teachings of the two documents one would learn

that good elasticity can be related to cysteine residues at the terminal regions of HMW glutelins and can be improved by repeating certain Glutamine rich domains in wheat, and that wheat flour is essential for obtaining raising flours and that the treatment with transglutaminase might further improve the viscoelastic characteristics of a dough comprising wheat dough and that transglutaminase should be added after grinding.

WO 98/08607 and US 6,517,874, alone or in combination, does not anticipate or render obvious the present invention. The two documents would not result in a non-allergenic, rising flour in accordance with the present invention because WO 98/08607 increases the potential allergenicity of the flour by repeating Glutamine rich domains and not mutating the allergenic domains, and US 6,517,874 does not eliminate wheat from the flour or preserve rising ability when the proportion of wheat flour is lowered. Among other failures, it is worth noting that the cited documents fail to teach or suggest preserving LKVAKAQQLAAQLPAMCR (SEQ ID NO: 11) in storage proteins encoded by transgenes derived from wheat because that C-terminal domain is linked to the effective action of transglutaminase. The latter would not be expressed from a transgene in the seed because the prior art teaches away from the presence of transglutaminase in seeds prior to grinding. Therefore, the present claims share the same or corresponding special technical features such as the selection of certain transgenes encoding wheat storage proteins along with co-expression of a transgene encoding transglutaminase.

Upon an indication that the elected claims directed to flours are allowable, the non-elected claims directed to transgenic plants, seeds, and their related processes would then have to be searched and examined. Delay in the examination of the non-elected claims would not result in compact prosecution, and is not in the public interest. Comparison of claims 1, 5 and 9 show that at least they (and claims depending therefrom) have unity of invention. Their related process claims should also be examined in this application in accordance with M.P.E.P. § 1850 III.

In the alternative, it is noted that the Examiner acknowledges that claims 1 and 4 are generic or linking claims. Thus, examination should proceed under the provisions of M.P.E.P. § 809. SEQ ID NOS: 36-44 are structurally related as individual species of

sequences for mutagenesis for wheat storage proteins. Examination of claims 1 and 4 require all of SEQ ID NOS: 36-44 to be considered.

Finally, under the Commissioner's Notice of March 26, 1996 (1184 OG 86) implementing the Federal Circuit's decisions of *In re Ochiai*, 37 USPQ2d 1127 (1995) and *In re Brouwer*, 37 USPQ2d 1663 (1996), Applicant requests rejoinder of the non-elected process claims upon an indication that an elected product claim is allowable.

Applicant earnestly solicits an early and favorable examination on the merits.

Respectfully submitted,

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